



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶: A61M 5/00, B32B 27/26, 27/30	A1	(11) International Publication Number: WO 99/26683 (43) International Publication Date: 3 June 1999 (03.06.99)
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(54) Title: A MEDICAL INSTRUMENT WITH A HYDROPHILIC, LOW-FRICTION COATING (57) Abstract <p>A low friction, multilayer lubricious coating for a medical instrument. The multilayer coating comprising a first layer (3) in contact with the surface of the medical instrument (2), and a second layer (4) sequentially applied to the surface of the medical instrument (2) without the use of organic solvents. Once both layers (3, 4) are applied to the surface of the instrument (2) and dried, they are simultaneously co-cured. This results in a composite coating in which the first and second polymer layers are physically held together without crosslinking or covalent bonds forming therebetween.</p> <div data-bbox="763 1155 1429 1701"> </div>		

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**A MEDICAL INSTRUMENT WITH A
HYDROPHILIC, LOW-FRICTION COATING**

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of co-pending U.S. Serial No. 07/955,746 filed April 29, 1993, which is incorporated by reference herein.

FIELD OF THE INVENTION:

The present invention relates to a medical instrument for insertion into a body cavity, such as a guide wire, having a lubricious, hydrophilic, low-friction coating. By providing a lubricious, hydrophilic, low-friction coating for medical instruments, insertion of such instruments into a body is facilitated and the risk of damaging body tissue is reduced.

BACKGROUND OF THE INVENTION:

U.S. Patent No. 4,642,267 to Creasy et al. discloses a low-friction coating composition that includes a blend of a first thermoplastic polymer of polyurethane having no reactive isocyanate groups and a second polymer of a hydrophilic poly (N-vinyl lactam). Low-friction coatings formed by such a polymer blend, however, suffer from the drawback that they do not adhere sufficiently well to e.g., guide wires, to prevent the coating from being scraped off during the bendings which such wires will be exposed to during use.

GB Patent Specification No. 1,600,963 discloses a method of providing an article with a hydrophilic coating by forming thereon a layer of polyurethane having reactive isocyanate groups and by reacting the polyurethane with polyvinylpyrrolidone to form a coating of a polyvinylpyrrolidone-polyurethane interpolymer.

EP Patent Publication No. 093,094 A1 discloses a method of providing the surface of a polymeric article with a hydrophilic coating having a low-friction coefficient when wet. In

this method, a solution of a compound containing at least two reactive isocyanate groups per molecule is applied to the polymeric article. Subsequently, a polyethyleneoxide solution is applied to the article and any solvent in the solution is removed by evaporation and curing of the coating at an elevated temperature.

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DK Patent Application No. 1709/83 discloses a method of forming on a polymer surface a hydrophilic coating having a low-friction coefficient. This coating is formed by applying to the polymer surface a solution containing a compound having at least two unreacted isocyanate groups per molecule. The solvent from the polymer solution is then evaporated followed by application to the polymer surface of a solution containing a polyvinylpyrrolidone and evaporation of its solvent. Finally, the coating is cured at an elevated temperature.

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A common feature of the coatings prepared by the methods described in GB Patent Specification No. 1,600,963; EP Patent Publication No. 093,094 A1; and DK Patent Application No. 1709/83 is that they involve the use of polyurethanes with reactive isocyanate groups. Such compositions suffer from the drawback that they can form aromatic carcinogenic amines by reaction with water. A further drawback of these methods is that in forming the coatings, it is necessary to use toxic organic solvents to exclude water in order to prevent an unintentional reaction with the reactive isocyanate groups.

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EP Patent Publication No. 166,998 A2 also discloses a method wherein an article is initially treated with a solution of a polymer having a reactive functional group in an organic solvent which serves to dissolve or swell either the article or a surface layer on the article. After evaporation of the solvent by drying, the article is treated with a solution containing a water-soluble polymer of a cellulosic polymer, a maleic acid anhydride polymer, a polyacrylamide or a nylon. Subsequently, the article is dried to remove the solvent before dipping the article into water to increase the affinity of the coating for water. The article is then dried.

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The use of organic solvents to form the inner layer of such low-friction coatings as set forth above creates both environmental and health problems. An object of the invention is to provide a method which allows the inner layer, as well as the outer layer to be formed without the use of organic solvents.

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Another object of the present invention is to provide a low-friction coating that adheres strongly to an instrument, including a metal instrument, to prevent the coating from being removed from the surface of the instrument during use. This adherence should be strong enough that the low-friction coating on, e.g. a guide wire, is not scraped off when a catheter is axially displaced relative to the guide wire.

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A further object of the invention is to provide a coating free of substances presenting a health risk in case parts of the coating are unintentionally released into the human organism, e.g. directly into the blood stream, during use of the coated instrument.

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Another object of the invention is to provide a multi-layer composite coating wherein the first and second layers are physically adhered to each other without the formation of covalent bonds or cross-linking therebetween.

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These and other objects which will appear from the following description are obtained with the method and compositions according to the invention.

SUMMARY OF THE INVENTION

The present invention is a medical instrument which has a composite coating that is lubricious when wet. The coating is formed from simultaneously curing first and second polymeric layers. The first layer is in direct surface contact with the medical instrument. The first layer includes a dried aqueous emulsion of a water-insoluble latex polymer. The second layer includes a dried aqueous solution of a hydrophilic polymer. The first and second layers form an integral composite coating through simultaneous heat curing in the absence of organic solvents and covalent bonding. The simultaneous cure of the first and second layers thus prevents cross-linking therebetween.

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In the present invention, the dried aqueous emulsion of the first layer may be an acrylic latex, such as for example an acrylate, a methacrylate, an acrylonitrile, an acrylamide, an acrylic acid or a methacrylic. The dried aqueous solution of the second layer can be carboxymethyl cellulose. Alternatively, the second layer can be chosen from, for example, a copolymer of maleic acid anhydride, vinyl ether and a polysaccharide.

A polymerization accelerator can also be incorporated into the first layer of the present invention. The polymerization inhibitor can include, for example melamin.

The instrument according to the present invention can include, for example, a guide wire having a metallic core. This guidewire is placed within a tubular polymeric body. The polymeric body can be formed from, for example, polyurethane and polyester block copolymers.

BRIEF DESCRIPTION OF THE DRAWINGS.

The present invention can be further understood with reference to the following description in conjunction with the appended drawings wherein like elements are provided with the same reference numbers. In the drawings:

Figure 1 is a top view of a coated guide wire prepared by the method of the invention.

Figure 2 is an enlarged cross sectional view along the lines 2-2 of the guide wire according to Figure 1.

DETAILED DESCRIPTION

The coated guide wire is generally designated 10 and includes a metallic core 1 which is tapered at its forward end so as to facilitate the manipulation of the guide wire.

The metallic core is surrounded by a polymer tube 2 which is heat sealed to the exterior surface of the metallic core 1. A first coating 3 made from an aqueous polymer

emulsion, such as an acrylic or polyether block amide latex, is coated onto polymer tube 2 and the first coating 3 is covered with a second coating 4 of a water soluble hydrophilic polymer.

Surprisingly, it has been found in the present invention that coatings prepared from a number of aqueous polymer emulsions (latexes) are capable of adhering to both plastic and metal surfaces after curing if the curing is effected after application of the second coating, and that a large number of hydrophilic polymers are capable of adhering to the inner latex layer. Thus, if the inner coating is cured prior to application of the second coating, the desired adherence is not obtained. A particularly preferred group of latexes are the acrylic latexes, such as latexes based on acrylates, methacrylates, acrylonitrile, acrylamide acrylic acid and methacrylic acid. Other types of latexes are also contemplated, including for example, isopren and styrene latexes. These latexes form satisfactorily adhering coatings under certain circumstances. The preferred aqueous emulsion (latex) has a dry matter content of 25%-60%. The polymer emulsion also may contain various additives to accelerate polymerization, such as a water-soluble resin, including for example, a melamin resin, in a concentration of about 5%.

In the present invention, the first coating composition is conveniently applied by dipping the instrument into the aqueous emulsion. The instrument is then withdrawn from the emulsion at a predetermined rate, e.g. 0.5 cm/sec., so as to obtain a desired thickness. The coating thus formed is subsequently dried. The drying may be effected by air-drying, e.g. at room temperature, or by heating to a temperature of up to the curing temperature of the latex, e.g. up to about 100°C, preferably about 40°C. The drying time will normally be from about 2 to about 20 minutes depending on the drying temperature. At a drying temperature of about 20°C, the drying time is typically about 15 minutes.

The second coating composition can include an aqueous solution of a water-soluble hydrophilic polymer. Examples of suitable hydrophilic polymers include the following:

- (1) Homopolymers or copolymers of acrylates; methacrylates; acrylonitrile; acrylamide, such as polyacrylamide products commercially available under the trade names

"Separan", "Purifloc", "Magnaflow" and "Hercules"; acrylic acid, such as polyacrylic acid products commercially available under the trade names "Carbopol", "Versicol" and "Primal"; and methacrylic acid.

5 (2) Carboxymethyl cellulose.

(3) Copolymers of maleic acid anhydride and vinyl ether, such as a product commercially available under the trade name "Gantrex".

10 (4) Polysaccharides, such as dextran.

The hydrophilic polymers of the present invention are preferably present in an aqueous solution in a concentration of from about 0.5% to 5% by weight, and preferably at about 1.25% by weight.

15 Application of the second coating is conveniently effected in the same manner as that of the first coating, i.e. by dipping the pre-coated instrument into an aqueous solution of the second coating and by withdrawing the instrument from the solution at a predetermined rate. Subsequently, the coating is dried, e.g. at room temperature, for a period of from about 5 to about 20 minutes.

20 As set forth above, curing of the inner and outer layers is carried out after the formation of the outer layer. Curing should be carried out at a temperature of above about 100°C, preferably at a temperature of above about 130°C-140°C. Curing, however, can take place at temperatures as high as 160°C-180°C, for up to 1 hour depending on the instrument and the components of the coating. It should be noted that the coating obtains the highest wear resistance by treatment at high temperatures.

25 After curing the instrument, it is optionally washed with water to remove additives, e.g. surfactants, if any. The water wash may take from a few minutes to about 24 hours. The instrument is then subjected to a final drying, e.g. at room temperature.

In another embodiment of the present invention, a medical instrument is provided which has a coating that becomes lubricious when wet. This coating is formed by simultaneously curing two polymeric layers which are applied and dried to the surface of the medical instrument in sequential fashion.

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The first polymeric layer is applied first and is in direct surface contact with the medical instrument. This layer is applied to the surface of the medical instrument as previously described. The second polymeric layer is then applied to the medical instrument over the first polymeric layer.

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Once both coatings are in place on the surface of the medical instrument, they are simultaneously co-cured at a temperature above about 100°C. Such a curing process forms the two polymeric layers into an integral composite coating composition in which the two layers remain distinct yet are physically adhered to each other.

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Moreover, the simultaneous co-curing of the first and second polymer layers takes place in the absence of organic solvents. Furthermore, the simultaneous co-curing of the first and second layers takes place without the formation of covalent bonds therebetween. Thus, by curing the first and second layers together, increased physical adhesion between the two layers is achieved compared to a process which cures the layers individually.

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In another embodiment of the invention, a guide wire is provided which includes a metallic core, such as a stainless steel core. A polymer tube is placed over the metallic core. The polymer tube is made from a polymer, such as for example, polyurethane and polyether block amides. The polymer tube is coated with an inner layer of an aqueous polymer solution, such as an acrylic polymer, and an outer layer of a hydrophilic coating of, for example, a polyacryl amide.

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The invention will now be described in further detail with reference to the following examples. These examples are presented for purposes of illustration only and are not intended to limit the present invention in any way.

30

EXAMPLE 1

5 A) A guide wire consisting of stainless steel having a diameter of 0.2 mm and wound into a coil with close windings having an outer diameter of 0.889 mm was cleaned by dipping into methylene chloride. Subsequently, a first coating containing a blend of the following was applied to the guide wire:

Acrylic latex, 50% dry matter content	230 g
Melamin resin, 80% dry matter content	6.5 g
Catalyst solution	5.0 g
10 Water	10.0 g

15 The catalyst solution included 5 g of oxalic acid, 26 g of dimethylamino ethanol and 69 g of water. The coating was applied by quickly dipping the guide wire into the blend and subsequently withdrawing it from the blend at a rate of 0.5 cm/sec.

20 The coating thus formed was air-dried at 20°C for 20 minutes followed by application of a further coating of a hydrocolloid solution consisting of 2.5 g of polyacrylamide ("Separan NP10", Dow Chemical Company) dissolved in 97.5 g water. The second coating was applied in the same manner as the first coating.

The coated guide wire was air-dried for 20 minutes and then cured by oven drying in a hot-air oven at 140°C for 40 minutes. Finally, the coated guide wire was cooled to ambient temperature.

25 (b) For comparison, a similar guide wire was coated with a prior art two-layer hydrophilic coating. The first layer of the coating included a polyurethane containing free isocyanate groups. The second layer of the coating included a copolymer of maleic acid and vinyl ether ("Gantrez AN 179" from GAF as described in Example 11 of EP Patent Publication No. 166 998). The friction of the coatings formed on the respective guide wires after wetting with
30 water was measured.

The measurement of friction on the respective guide wires was carried out with a measuring apparatus that included a rotatable disc mounted on a horizontal axis having a diameter of 100 mm and a width of 20 mm. The periphery of the disc was covered with synthetic wash leather which was maintained in a wet state by keeping the disc dipped in a water bath over about 15 mm of the periphery of the disc. The disc was driven by an electric motor at 60 r.p.m.

To measure the friction on the guide wires, one end thereof was secured to a spring dynamometer. The other end of the guide wire was placed around the rotating disc in the direction of rotation, facing a clamp which, via a pull string placed across a pulley and loaded with weights, could generate a given static pull on the guide wire.

The guide wire was in contact with the wet wash leather over 180° of the periphery of the disc. The weight load produces a given pull force (pre-stress) which in the following formula below is designated P2. The friction between the guide wires and the disc produces an extra force which can be recorded on the dynamometer. In the formula below, this force is designated P1.

The coefficient of friction can be calculated on the basis of the following formula:

$$\mu = \frac{\ln(P1/P2)}{\pi}$$

The friction of the coating according to the present invention was measured at four different pre-stress loads (=P2), viz. 0.2, 0.7, 1.7 and 3.58 Newtons. Measurement of the friction generated on the prior art coating was carried out at three different pre-stress loads, viz. 0.7, 1.7 and 3.58 Newtons. The results obtained from these friction tests are set forth in Tables 1 and 2 below.

Table 1**Measurement of Friction of Coating According to the Invention**

5	Recorded force (=P1), N	0.25	0.9	2.3	4.6
	Pre-stress load (=P2), N	0.2	0.7	1.7	3.58
	Coefficient of friction, μ	0.07	0.08	0.09	0.08

Table 2

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Measurement of Friction of Prior Art Coating

	Recorded force (=P1), N	0.96	2.75	4.5
	Pre-stress load (=P2), N	0.7	1.7	3.58
15	Coefficient of friction, μ	0.10	0.09	0.07

As the data from Tables 1 and 2 indicate, the coating according to the invention produces a friction which is essentially the same as the friction obtained with the prior art coating.

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EXAMPLE 2

A number of guide wires of stainless steel were coated with separate latex coatings in the manner set forth in Example 1.

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Two commercially available acrylic latexes were used, i.e. "Polysar latex 6779" marketed by Polysar Nederland B.V. and "Acronal LN579S" marketed by BASF AG.

In certain cases, latexes blended with melamin resin as set forth in Example 1 were used. Other latexes were used as delivered (e.g., 50% dry matter content) but diluted to a 40% dry matter content.

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The coated guide wires were dipped into aqueous solutions of the hydrocolloids set forth in Example 3 below. After air drying, the coatings were cured at 130-140°C for 30 minutes. Subsequently, the guide wires were dipped into water and the coefficient of friction was determined in the manner set forth above. The results obtained are set forth in Table 3.

Table 3 - Coefficient of Friction of Coatings Based on Acrylic Latexes

Test No.	Latex	Melamin	Hydrocolloid	Pre-Stress Load (= P2), N			
				0.2	0.7	1.7	3.58
1	Acronal LN579S		Separan NP20 ¹⁾	0.13	0.13	0.13	0.12
2	-	+	-	0.13	0.14	0.13	0.10
3	-		Separan NP10 ²⁾	0.07	0.08	0.07	0.08
4	-		-	0.07	0.08	0.09	0.08
5	-	+	-	0.07	0.13	0.15	0.18
6	-		Versicol S 25 ³⁾	0.07	0.18	0.21	0.19
7	Polysar 6779		Versicol WN23 ⁴⁾	0.12	0.11		
8	-	-	-				
9	Acronal LN579S		Versicol W 17 ⁵⁾	0.16	0.17	0.18	
10	-		-	0.86			
11	-		Separan NP10 ²⁾	0.86			
12	-		Carbopol 907 ⁶⁾	0.07	0.14	0.15	0.14
13	-		CMC 9H4 ⁷⁾	0.18	0.14	0.14	0.12
14	-		Dextran ⁸⁾	0.13	0.13	0.13	0.16
15	-		Versicol F25 ⁹⁾	0.18	0.16		
16	-		Magnafloc. 351 ¹⁰⁾	0.13	0.26	0.26	

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- 1) "Separan NP20" is a non-ionic acrylamide polymer marketed by Dow Chemical Company.
- 2) "Separan NP10" is an acrylamide copolymer having a molecular weight of 1×10^5 to 3×10^5 marketed by Dow Chemical Company.
- 3) "Versicol S 25" is a polyacrylic acid having a molecular weight of about 20×10^6 marketed by Allied Colloids.
- 4) "Versicol WN23" is the sodium salt of a polyacrylamide having a molecular weight of 7.5×10^6 marketed by Allied Colloids.
- 5) "Versicol W 17" is a polyacrylamide having a molecular weight of about 500,000 marketed by Allied Colloids.
- 6) "Carbopol 907" is a linear polyacrylic acid marketed by Union Carbide.
- 7) "CMC 9H4" is carboxymethyl cellulose marketed by Hercules.
- 8) "Dextran" is type T 2000 marketed by Pharmacia.
- 9) "Versicol F25" is an acrylamide copolymer having a molecular weight of 1.3×10^7 marketed by Allied Colloids.
- 10) "Magnaflow 351" is a polyacrylamide marketed by Allied Colloids.

As Table 3 indicates, Separan NP10 produces the lowest coefficient of friction, whereas the other hydrocolloids produce coefficients of friction which are slightly higher but fully satisfactory for a number of purposes.

In order to illustrate the good adhesive properties of the coatings of the present invention, a scraping test was performed using an apparatus having two catheter tips. One of the catheter tips was secured to a movable block. The other catheter tip was secured to a fixed block of acrylic plastic. In this way, the angle between the axes of the catheter tips was adjusted while at the same time keeping the axes constantly spaced.

5 By pulling a wet guide wire coated with a low-friction coating according to the present invention through the two catheter tips placed at different angles, it was possible to determine under a stereo microscope the angle at which the coatings started to be scraped off from the edge of one of the catheter tips. The greater the angle between the catheter tips at the beginning of the scraping, the greater the adherence. The maximum obtainable angle was 45°.

A number of coatings according to the invention prepared as set forth in Example 2 were compared with a prior art coating as set forth in Example 1. The results of these tests are summarized in Table 4 hereinbelow.

Table 4 - Determination of Adherence Based on Scraping Angles

	<u>Test No.</u>	<u>Latex</u>	<u>Melamin</u>	<u>Hydrocolloid</u>	<u>Catheter Angle in Degrees</u>				
5	17	Acronal LN579S		Separan NP20	30	35	35	30	35
	18	-	+	-	35	35	30	35	35
	19	-		Separan NP10	45	45	45	45	45
	20	-		-	45	45	45	45	45
	21	-	+	-	45	45	45	45	45
10	22	-		Verisicol S 25	25	20	20	20	15
	23	Polysar 6779		Verisicol WN23	20	20	20	25	25
	24	Acronal LN579S		Verisicol W 17	20	20	30	30	35
	25	-		-	45	45	45	45	45
	26	-		Carbopol 907	20	30	30	40	30
15	27	-		CMC 9H4	40	40	40	45	40
	28	-		Dextran	35	35	35	40	40
	29	-		Versicol F25	20	20	20	25	25
	30	-		Magnafloc. 351	15	10	5	5	10
	31	Prior Art Coating			4	6	3	5	3
20									

As the data from Table 4 indicates, the adherence of the coatings according to the present invention is generally considerably higher than the adherence of the prior art coatings.

EXAMPLE 3

5 A stainless steel guide wire as described in Example 1 was coated with a first layer of a dispersion of an aromatic polyurethane ("Neo Rex R 940, marketed by Polyvinyl Chemie) and having a dry matter content of 35%. After drying, the coated guide wire was coated with a second layer of a 1% aqueous solution of a polyacrylamide ("Versicol WN23") in water in the same manner as described in Example 1. The coated guide wire was dried in air for 30 min. and was subsequently cured at 145° C for 30 min.

10 The coated guide wire was then soaked in water for 30 sec. and the friction was evaluated manually by moving fingers over and in contact with the coating. The friction was found to be similar to the friction of the coating of the invention described in Example 1.

EXAMPLE 4

15 A thin polyurethane tube ("Pellethane 2363" marketed by Dow Chemical Company) having an inner diameter of 0.4 mm and an outer diameter of 0.85 mm was introduced onto a guide wire core of stainless steel having an external diameter of 0.4 mm so as to fully cover the guide wire core. The core and tube were then heated to about 185°C for 5 min. to heat
20 seal the tube to the metallic core.

A first coating composition was prepared. This coating composition contained a mixture of:

25	Acrylic latex ("Acronal LN 5795"), 50% dry matter	400 g
	Water	100 g

This first coating was applied to the guide wire by quickly dipping it in the coating composition and subsequently withdrawing it therefrom at a rate of 0.5 cm/sec. This coating was air dried for 30 min. at 20°C.

5 A second coating composition was then prepared. This second coating composition contained:

Polyacrylamide ("Versicol WN 23")	10 g
Water	1000 ml

10 This second coating composition was applied on top of the first coating in the same manner as the first coating composition. The guide wire was air dried for 30 min. and was then cured at 160°C for 1 hour before it was cooled to ambient temperature.

15 Following wetting with water, the friction of the coating was measured as described in Example 1. The results of these tests are set forth in Table 5 hereinbelow.

Table 5 - Measurement of Friction of Coating According to the Invention.

20	Recorded force (=P1), N	0.9
	Pre-stress load (=P2), N	0.7
	Coefficient of friction, μ	0.08

25 The adherence of the coating of Example 4 was determined by the scraping test described above. The results of this test are set forth in Table 6 hereinbelow.

Table 6 - Determination of Adherence Based on Scraping Angles.

Test No.	Latex	Hydrocolloid	Catheter Angle in Degrees
Example 4	Acrylic	Polyacrylamide	30, 30, 35, 35, 35

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EXAMPLE 5

10 A guide wire similar to that of Example 4 was prepared except that the thin tube was made from a polyether block amide ("Pebax" marketed by Atochem). This guide wire was then tested and showed similar friction data as set forth in Table 5.

EXAMPLE 6

15 A series of microscope slides made from glass were dipped into a latex of the same composition as the first latex coating composition described in Example 4. After drying, the coated slides were dipped into a solution of the same composition as the second polyacrylamide coating composition described in Example 4.

20 The coating thus formed was dried for 30 min. at room temperature and was subsequently cured in an oven for 30 min. at a temperature of 160°C. The coated slides were weighed and then washed with sterile water by moving a finger over the coating for about 2 min. on each side.

The friction coefficient of these slides was tested and was found to be essentially the same as the friction coefficient of the coating described in Example 4.

5 The slides were dried and weighed again. The washing of the slides resulted in a weight loss of only 0.0001 g (from 4.6208 g) which shows that the adherence of the hydrophilic coating of the present invention to the glass surface is excellent.

10 The invention being thus described, it will be obvious that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the invention and all such modifications are intended to be included within the scope of the following claims.

WHAT IS CLAIMED IS:

1. A medical instrument having a lubricious coating when wet, said coating being formed from simultaneously curing first and second polymeric layers, said first layer being in direct surface contact with said medical instrument and comprising a dried aqueous emulsion of a water-insoluble latex polymer and said second layer comprising a dried aqueous solution of a hydrophilic polymer, whereby said first and second layers form an integral composite coating through simultaneous heat curing in the absence of organic solvents and without covalent bonding and cross-linking between said first and second layers.
2. The instrument according to claim 1 wherein said first layer is a dried aqueous emulsion of an acrylic latex.
3. The instrument according to claim 2 wherein said acrylic latex is selected from the group consisting of acrylates, methacrylates, acrylonitriles, acrylamides, acrylic acid and methacrylic acid.
4. The instrument according to claim 1 wherein said hydrophilic polymer in said second layer is a dried aqueous solution of a homopolymer or copolymer of a material selected from the group consisting of acrylates, methacrylates, acrylonitriles, acrylamides, acrylic acid and methacrylic acid.
5. The instrument according to claim 1 wherein said second layer is a dried aqueous solution of a carboxymethyl cellulose.
6. The instrument according to claim 1 wherein said second layer is a dried aqueous solution of a material selected from the group consisting of a copolymer of a maleic acid anhydride, vinyl ether and a polysaccharide.

7. The instrument according to claim 1 wherein there is further incorporated a polymerization accelerator in said first layer.

5 8. The instrument according to claim 7 wherein said polymerization accelerator is melamin.

9. The instrument according to claim 1 wherein said instrument is a guide wire having a metallic core placed within a tubular body of a polymer selected from the group consisting of polyurethanes and polyester block copolymers.

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FIG-1

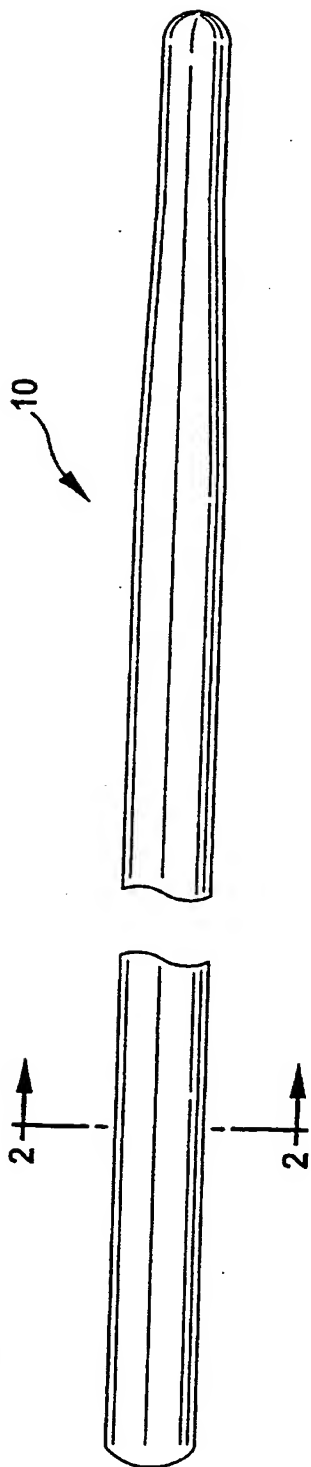
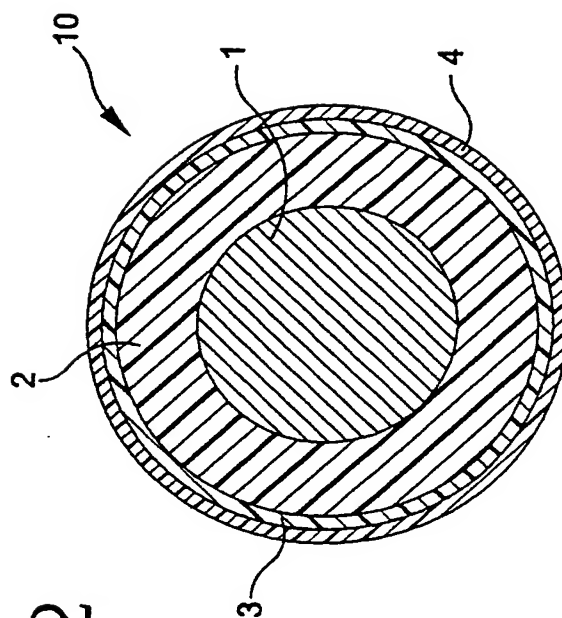


FIG-2



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/24277

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 5/00; B32B 27/26, 27/30

US CL : 428/ 461, 515, 520; 604/93,172,363

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 428/ 461, 515, 520; 604/93,172,363

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
None

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS: "lubricat? or lubricaious" and "medical" and "latex or aqueous or emulsion"

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,876,126 A (TAKEMURA et al.) 24 October 1989, see the entire document especially column 3, lines 46+.	1-9
X --- A	US 5,509,899 A (FAN et al.) 23 April 1996, see figure 3, layers 11 and 12, see also column 3, lines 7-50, column 5, lines 10-35, and the examples.	1, 2, 6 --- 3-5, 7-9
X --- A	US 5,272,012 A (OPOLSKI), 21 December 1993, see the entire document especially column 5, and column 6, lines 10-20.	1-3 --- 4-8
X,P	US 5,749,837 A (PALERMO et al.) 12 May 1998, see figure 9, and column 13, lines 5+.	1, 9



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
B earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

15 FEBRUARY 1999

Date of mailing of the international search report

02 MAR 1999

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